REMARKS

In the Office Action the Examiner first rejected Claims 2, 4-5, 13-16, 19, 21, and 23-24 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, applicant has amended Claims 2 and 5 to depend on Claim 1. Claim 4 has been canceled. Additionally, Claim 13 has been amended to reintroduce the expression "natural, synthetic or semisynthetic polymer" in place of the expression "natural ~ synthetic". This amendment finds complete support in the originally filed Claim 13, and in the original specification, page 5, 1st paragraph. Next, applicant amended Claim 21 to refer to "4,4'-methylenebis" rather than "4,41-methylenebis". Lastly, Claim 23 has been canceled and Claim 24 has been amended to depend from Claim 20. Removal of the rejections under 35 U.S.C. 112, second paragraph is therefore requested.

The Examiner then rejected Claims 37 and 38 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement. In response, applicant has canceled Claims 37 and 38. Therefore, the rejections of Claims 37 and 38 are rendered moot.

The Examiner then reminded applicant of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that are not commonly owned at the time a later invention was made.

Next, the Examiner rejected Claims 1, 2, 4-21, 23-34, and 37-38 under 35 U.S.C. 103(a) as being unpatentable over Balazs et al ('865) in view of WO 95/25752 and Halpern et al. ('114). Applicant respectfully requests removal of the rejection and reconsideration.

In Balazs, as noted by the Examiner, the covalent bonding of sodium hyaluronate to polyurethane is disclosed. However, Balazs is "silent regarding the sulphate modification of the hyaluronic acid component". Furthermore, as per the Declaration by Dr. Renier submitted herewith, the process taught by Balazs in Example 3 to form the covalent bonding in question is completely different from the present processes, and it would be unable to be carried out with sulphated hyaluronic acid derivatives because of the chemical reasoning given in the above referenced Declaration. Therefore, Balazs does not teach nor suggest how to bind covalently polyurethane to the present sulphated hyaluronic acid derivatives.

Additionally, in order to better define the claimed invention in view of Balazs, Claims 1 and 20 have been amended to limit the claimed sulphated derivatives to the O-sulphated derivates having the -OH groups not free to react with the activation agent disclosed by Balazs, thus excluding the N-sulphated derivatives.

In regards to WO 95/25751, the sulphated derivatives of the present application are disclosed. However, no actual teaching to bind them with polyurethane can be found in the document. The specific passage cited by the Examiner in line 20,

page 28 of WO 95/25751 cites polyurethane amongst a plethora of polymeric compounds and regards the possibility of administering sulphated hyaluronic acid derivatives in association with other chemical polymers, amongst which is polyurethane.

No reference is made in WO 95/25751 to the possibility of covalently binding polyurethane with sulphated hyaluronic acid derivatives and, as explained above, the teachings to do this could not be found in Balazs.

The Halpern reference would not help a person skilled in the art who was aware of Balazs to arrive at the present claimed invention. Halpern discloses how to ameliorate the lubricity and wetting characteristics of plastics by coating them with hydrophilic materials. For example, Halpern teaches to form a mucopolysaccharide film, such as a hyaluronic acid film, on the surface of a plastic material by cross-linking of grafting the mucopolysaccharide film on the plastic surface.

Nowhere in Halpern are sulphated hyaluronic acid derivatives mentioned, however reference is made to hyaluronic acid and chondroitin sulphate amongst various mucopolysaccharide of possible use.

Even if Halpern were to cite polysaccharides similar to the present sulphated derivatives, the teachings of Halpern regarding the way these products may bind to the plastics indicate a completely different reaction from the present invention. See, for example, Halpern at column 4, lines 28-37: "The molecules of any polysaccharide chosen will contain hydroxyl groups through which crosslinking can be accomplished, for example with

di- or poly-isocyanates. Hyaluronic acid, specifically, contains also a plurality of carboxyl groups through which ionic crosslinking reactions are possible, for example with polyvalent cations. Chondroitin sulphate contains not only hydroxyls as reactive groups, but also acid sulphate groups."

The bonding between plastic material and the mucopolysaccharide is a crosslinking between all the reactive groups present, and it occurs only on the surface of plastics, whereas the present processes in solution wherein a covalent bonding between the carboxyl groups of a hyaluronic acid derivative (and not the sulphate groups) form a covalent binding with polyurethane through a spacer.

The differences highlighted above between the present processes and those disclosed by the cited prior art are not immaterial because they allow the obtaining of a final product which maintains the desired anticoagulant characteristics of sulphated hyaluronic acid derivative not bound to polyurethane.

In light of the foregoing applicant respectfully submits that that the claims of the present application are in proper form for allowance.

An early and favorable action is earnestly solicited.

Respectfully submitted,

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